

**REMARKS**

Claims 1-9, 11, 12 and 14-25 are pending in the above-identified application. Support for new claims 23-25 is found at page 5, lines 11-38.

**Removal of Issue under 35 USC 112**

Claim 16 has been rejected under 35 USC 112, first paragraph, because this claim recites a “prevention” method. Claim 16 has been amended so as to remove this embodiment. Thus, the basis for this rejection has been removed such that this rejection should be withdrawn.

**Present Invention and Its Advantages**

The present invention, as recited in the present claims, is directed to a composition formulated for oral administration, which includes at least the combination of at least one marrow oil and at least one borage oil. The composition of the present invention may additionally contain a nettle extract and a soybean extract. The composition of the present invention unexpectedly and advantageously may be used to treat conditions such as alopecia by significantly increasing the anagenic/telogenic ratio. This is evidenced by the comparative test results described in the present specification and summarized in attached Annex 1. Following the protocol described at pages 11-15 of the present specification, volunteers were administered formulations containing different components as summarized at page 12 of the present specification. As shown in Annex 1, and as summarized in Table 1 at page 13 of the specification, Groups 5-8 (administered combinations of active components) exhibited significantly, advantageously enhanced anagenic/telogenic ratios over Groups 1-4 which were each administered the active components separately. This constitutes significant evidence of unexpected, advantageous properties exhibited by the compositions of the present invention.

Issues under 35 USC 102(b)

Claims 1-3, 5, 13 and 15 have been rejected under 35 USC 102(b) as being unpatentable over Deckers '337 (US 2002/0106337). This rejection is traversed based on the following reasons.

As correctly noted in the Office Action of January 23, 2007, the presently claimed invention is directed to a composition which requires the presence of both marrow oil (or "Cucurbita pepo seed oil") and borage oil. It is additionally noted that the present claims now recite that the composition is formulated for "oral" administration.

Deckers '337 discloses a variety of emulsion formulations which include "oil bodies" that may be prepared from plant seeds. Deckers '337 discloses in paragraph [0002] that the described formulations are "topically applied". Deckers '337 discloses in paragraph [0053] that the plant seeds from which the oil bodies may be obtained includes "borage" and "squash (*cucurbita maxima*)" among about 54 possible plant species, as well as "mixtures thereof". Deckers '337 also discloses that soybean (*Glycine max*) is another possible plant species from which oil may be used. In this regard it is noted that the number of possible combinations, as well as the number of components in each combination, from the approximately 54 different components disclosed in paragraph [0053] is not limited by Deckers '337. Thus, the number of possible combinations, including mixtures containing at least two up to 54 components, numbers well into the tens of thousands, if not hundreds of thousands. For example, the number of possible two-component mixtures alone is over 1, 300 while the number of three-component mixtures is over 23, 000. Note that one may form mixtures of up to 54 components.

Deckers '337 fails to disclose any specific combination of borage and marrow oil as employed in the composition of the present invention. In fact, Deckers '337 fails to provide any basis for a suggestion to one skilled in the art to combine these two specific oils from among the thousands of possible combinations disclosed, for example, in paragraph [0053] as noted above. Deckers '337 discloses that the described formulations are for "topical" application which contrasts with "oral" administration type formulations of the present invention. Consequently, numerous significant patentable distinctions exist between the present claims and Deckers '337

such that there fails to be any basis for asserting anticipation. Consequently, the above-noted anticipation rejection should be withdrawn because Deckers '337 fails to disclose each and every element as set forth in the present claims. *Verdagaal Bros. v. Union Oil Co. of California*, 814 F. 2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP 2131, Rev. 5, August 2006, p. 2100-67.

Issues Under 35 USC 103(a)

Claims 1-3, 5-7, 9, 13, 15, 20 and 21 have been rejected under 35 USC 103(a) as being unpatentable over Deckers '337.

Claims 1-22 have been rejected under 35 USC 103(a) as being unpatentable over Deckers '645 (USP 6,146,645).

Claims 1-19 have been rejected under 35 USC 103(a) as being unpatentable over Deckers '645, Duranton '421 (USP 6,465,421), Francis '748 (USP 5,695,748), and Segelman '893 (USP 6,017,893). These rejections are traversed based on the following reasons.

Deckers '645 discloses a variety of emulsion formulations formed from oil that may be obtained from plants as described at column 7, lines 26-49. Deckers '645 further discloses these formulations may be prepared in the form of a food product as noted at column 3, lines 35-41.

Deckers '645 fails to disclose or suggest anywhere the use of a borage oil as required in all of the composition of the present invention. Thus, Deckers '645 fails to satisfy the minimum basic requirements for alleging *prima facie* obviousness. *In re Vaeck* 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP 2143, Rev. 5, August 2006, p. 2100-126. In addition, Deckers '645 fails to recognize the unexpected, advantageous properties achieved by the present invention as evidenced by the comparative test results discussed above. Consequently, significant patentable distinctions exist between the present invention and Deckers '645 such that this basis for the above rejection should be withdrawn. In addition, even assuming that *prima facie* obviousness has been properly alleged, such obviousness has been rebutted by the comparative test results discussed above.

All of Duranton '421, Francis '748 and Segelman '893 fail to disclose or suggest the use of marrow oil in a composition, as recited in present claim 1 and required by all of the presently pending claims. Thus, the above-noted rejection fails to support an allegation of obviousness under 35 USC 103(a), since the applicable cited references fail to disclose all of the elements recited in the present claims. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 Fed. Cir. 1991). Consequently, it is requested that the above-noted rejection be withdrawn.

It is further submitted in addition to the above that there fails to be any reasonable suggestion or motivation for one skilled in the art to combine selected components from Deckers '645 with any of the Duranton '421, Francis '748 and Segelman '893 references .

Deckers '645 fails to mention the presence of borage oil. Further, all of these references fail to provide any reasonable suggestion whatsoever regarding the unexpected, advantageous properties evidenced by the comparative test results summarized in Annex 1 and in the present specification as discussed above. Consequently, even if a *prima facie* case of obviousness has been properly alleged, such obviousness has been rebutted by the evidence of unexpected, advantageous properties supported by the comparative test discussed above. *In re Kollman*, 595 F. 2d 48, 201 USPQ 193 (CCPA 1979). In *Kollman*, the submission of evidence showing the unexpectedly advantageous properties of the claimed combination supported a decision in favor of patentability, despite the disclosure in the prior art of the separate components and some general suggestions that one skilled in the art could consider combining the components together.

It is submitted for the reasons above that the present claims define patentable subject matter such that this application should now be placed in condition for allowance.

If any questions arise in the above matters, please contact Applicant's representative, Andrew D. Meikle (Reg. No. 32,868), in the Washington Metropolitan Area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By \_\_\_\_\_

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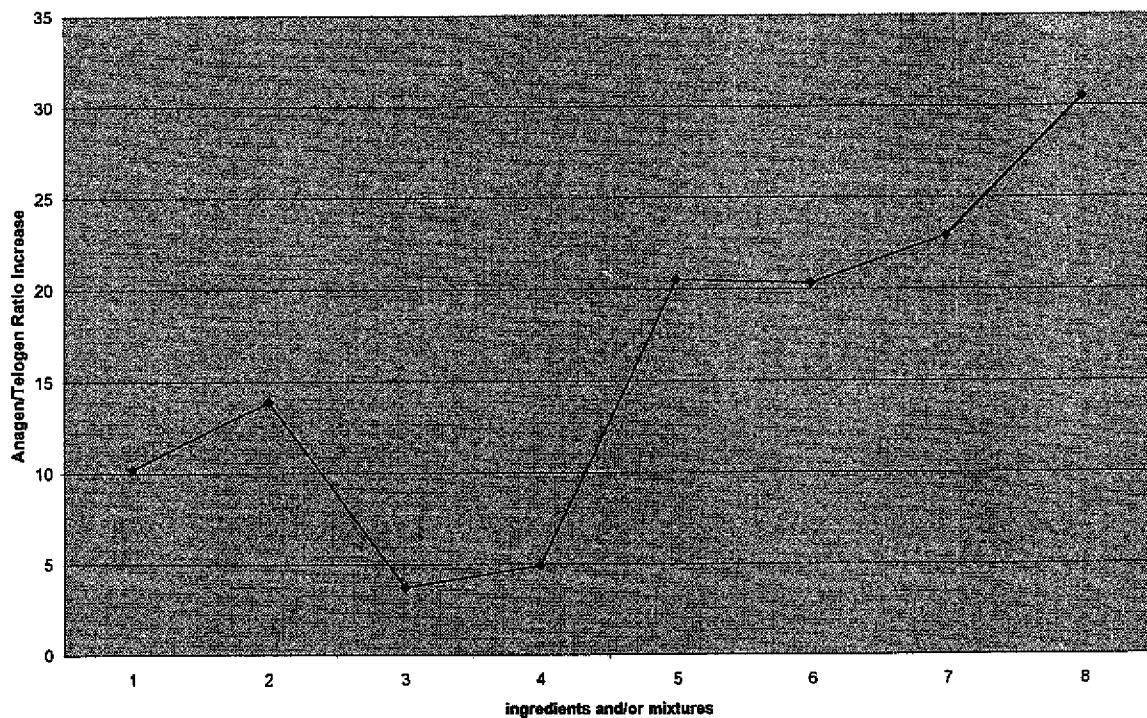
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Enclosures: Annex 1

## ANNEX 1



- 1= Cucurbita pepo seed oil (200mg): no significant increase
- 2= Stinging nettle root aqueous extract (200 mg): no significant increase
- 3= Borage oil (150 mg): no increase
- 4= Soy lecithin (20 mg): no increase
- 5= Cucurbita pepo seed oil (200mg)+ Borage oil (150 mg): strong increase
- 6= Cucurbita pepo seed oil (200mg)+ Stinging nettle root aqueous extract (200 mg)+ Borage oil (150 mg): strong increase
- 7= Cucurbita pepo seed oil (200mg)+ Stinging nettle root extract (200 mg)+ Borage oil (150 mg)+ Soy lecithin (20 mg), with simple mixture of the 4 components: strong increase
- 8= Cucurbita pepo seed oil (200mg)+ Stinging nettle root extract (200 mg)+ Borage oil (150 mg)+ Soy lecithin (20 mg), with maceration at 70°C during 2 hours of the nettle root powder in the mixture:cucurbita pepo seed oil+borage oil+lecithin: very strong increase